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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,534	02/13/2001	Andrew H. Cragg	9500100.APP	1509

20995 7590 08/23/2004

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

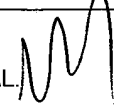
ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/782,534	Applicant(s) CRAGG ET AL. 	
	Examiner Kathryn Odland	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 12-14, 18, 20, 22, 25, 28-31, 33-44 and 48-52 is/are pending in the application.
- 4a) Of the above claim(s) 7, 12-14, 22, 25, 28-31, 33-44 and 50-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated May 24, 2004. Claims 1-5, 7, 12-14, 18, 20, 22, 25, 28-31, 33-44, and 48-52 are pending. Claims 7, 12-14, 22, 25, 28-31, 33-44, and 50-52 are withdrawn from consideration.

Response to Arguments

1. Applicant's arguments filed May 24, 2004 have been fully considered but they are not persuasive.

Applicant has amended claim 1 to include the limitation, "an anterior tract sheath **having a shaped distal end with an engagement structure** for engaging an anterior surface of the sacral vertebral body, wherein the shaped distal end of the anterior tract sheath facilitates anchoring of the anterior tract sheath into the anterior surface of the sacral vertebral body from a para coccygeal skin access point." However, applicant has failed to adequately define structure that would define over the prior art of record. For example, applicant argues. "Reiley et al. do not teach an anterior tract sheath having a distal end, such as, for example, **an angled or beveled distal end....**" However, an angled or bevel distal end is not a claim limitation and certainly the distal end of Reiley et al. can be considered to have a distal end with an engagement structure for any portion of the distal end of the sheath can be an engagement structure. The sheath has the capability of engaging, and thus, can be considered to have an engagement structure. The rejection is reiterated below.

2. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., angled or beveled distal end) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Information Disclosure Statement

The MPEP states the following with respect to large information disclosure statements:

*Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a **section that is highly relevant to patentability** or where a large number of documents are submitted and **applicant is aware that one or more is highly relevant to patentability**. -- M.P.E.P. § 609 (emphasis added).*

"Aids to Compliance With Duty of Disclosure," item 13:

It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. -- M.P.E.P. § 2004 (emphasis added).

Therefore, it is recommended that if any information that has been cited by Applicant in the Information Disclosure Statement(s) is known to be material to patentability as defined by 37 C.F.R. § 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents.

Further, the IDS submissions in Paper No. 8-11 have not been considered since the copy of the references was not present in the file. If these IDS submissions are to be considered a copy of the references along with a statement of relevance for each reference cited is requested.

Specification

3. The disclosure is objected to because of the following informalities: on page 2 in the cross-reference information, the date missing is required.

Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-5, 48 and 49 are rejected under 35 U.S.C. 102(e)/103(a) as being anticipated by Reiley et al. in US Patent No. 6,440,138.

Regarding claim 1, Reiley et al. disclose a discectomy apparatus for performing a discectomy of an intact or damaged intervertebral spinal disc, the intervertebral spinal disc having a disc body formed of a nucleus and annulus the apparatus having an elongated discectomy instrument (such as 22, 110, etc. and their respective associated

components) having a discectomy instrument body extending between a discectomy instrument proximal end and instrument distal end, a cutting head (such as 22, 110, etc.) located in a distal portion of the discectomy instrument, the instrument body and cutting head dimensioned to fit within and to extend through the axial bore, and means (such as via expansion and bending) for extending the cutting head laterally away from the axial disc opening toward or through the annulus of the intervertebral spinal disc; and operating means (such as 56) coupled to the instrument body proximal end for operating the cutting head to form a disc cavity within the annulus, the disc cavity extending laterally and away from the disc opening within the annulus, or to form a disc space by further extension of the disc cavity through at least a portion of the annulus, as recited in columns 3-7 and seen in figures 3-29. Regarding the phrase, *"through a trans-sacral axial bore extending cephalad and axially from a sacral position of a sacral vertebral body through one or more vertebral body and through a vertebral body endplate and axial disc opening into the nucleus of the intervertebral spinal disc"* functional language does not hold patentable weight in an apparatus claim. Thus, given the structure of Reiley et al. the device is capable of performing in a bore made in any orientation. Further, Reiley et al. disclose an anterior tract sheath **having a shaped distal end with an engagement structure** for engaging an anterior surface of the sacral vertebral body, wherein the shaped distal end of the anterior tract sheath facilitates anchoring of the anterior tract sheath into the anterior surface of the sacral vertebral body from a para coccygeal skin access point." Given applicant's broad recitation, the distal end of Reiley et al. can be considered to have a distal end with an

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engagement structure for any portion of the distal end of the sheath can be an engagement structure. The sheath has the capability of engaging, and thus, can be considered to have an engagement structure.

Regarding claim 2, Reiley et al. disclose that as applied to claim 1, as well as, aspiration means for aspirating the disc cavity or disc space, as recited in column 7, lines 10-25, for example.

Regarding claim 3, Reiley et al. disclose that as applied to claim 1, as well as, a cutting head having a fragmenting element for fragmenting the nucleus or annulus into fragments, as recited in columns, 1-7.

Regarding claim 4, Reiley et al. disclose that as applied to claim 3, as well as aspiration means for aspirating nucleus or annulus fragments from the disc cavity or disc space, as recited in column 7, lines 10-25, for example.

Regarding claim 5, Reiley et al. disclose that as applied to claim 3, as well as, irrigation means for delivering irrigation fluid into the disc cavity or disc space; and aspiration means for aspirating the nucleus fragments and irrigation fluid from the disc cavity or disc space, as recited in column 7, lines 10-25, for example.

Regarding claim 48, Reiley et al. disclose that as applied to claim 1, as well as, means for accessing (via 34 and 12) a sacral position of a sacral vertebral body; and means operable from the accessed sacral position for boring a trans-sacral axial bore cephalad and axially through a series of adjacent vertebral bodies and any intervening spinal discs, as recited in columns 2-7. Further, functional language does not hold patentable weight in an apparatus claim. Further, the apparatus of Reiley et al. is capable of performing the function.

Regarding claim 49, Reiley et al. disclose that as applied to claim 1, as well as, means for accessing an anterior surface of the sacral vertebral body (via 34 and 12); and means operable from the accessed anterior surface for boring a transsacral axial bore cephalad and axially through the vertebral bodies of a series of adjacent vertebral bodies and any intervening spinal discs and into or through the selected spinal disc providing at least a caudal axial disc opening into the nucleus of the selected spinal disc, as recited in columns 2-7. Further, functional language does not hold patentable weight in an apparatus claim. Further, the apparatus of Reiley et al. is capable of performing the function.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700